TITLE 18. BOARD OF EQUALIZATION

The State Board of Equalization Proposes to Adopt Amendments to California Code of Regulations, Title 18, Section 1591, *Medicines and Medical Devices*

NOTICE IS HEREBY GIVEN that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*. The proposed amendments clarify Regulation 1591, subdivision (a)(9), by providing that products approved by the United States Food and Drug Administration (FDA) means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, and by providing that medicines are further defined in subdivisions (b) and (c). The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers , are included in the definition of medicines under Regulation 1591, subdivision (b)(2). The proposed amendments clarify that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision of Regulation 1591. In addition, the proposed amendments make non-substantive changes to the regulation to make the regulation grammatically correct and internally consistent.

PUBLIC HEARING

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on April 28-30, 2015. The Board will provide notice of the meeting to any person who requests that notice in writing and make the notice, including the specific agenda for the meeting, available on the Board's Website at *www.boe.ca.gov* at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:30 a.m. or as soon thereafter as the matter may be heard on April 28, 29, or 30, 2015. At the hearing, any interested person may present or submit oral or written statements, arguments, or contentions regarding the adoption of the proposed amendments to Regulation 1591.

AUTHORITY

RTC section 7051

REFERENCE

RTC sections 6006, 6369, and Health and Safety Code sections 1200, 1200.1, 1204.1 and 1250.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

> "Medicines" means:
>
> > (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or
> >
> > (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure,

mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. . . ." Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that "medicines" means and includes:

(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable

urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation 425.0580 (9/1/65)). Furthermore, the FDA's website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."

- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."

Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applier as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

Interested Parties Process

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr.

Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph] would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

November 19, 2014, BTC Meeting

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff

also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the

type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition**,** the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.

NO MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

NO COST OR SAVINGS TO ANY STATE AGENCY, LOCAL AGENCY, OR SCHOOL DISTRICT

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California.

NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

The Board has made an initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendments to Regulation 1591 may affect small business.

NO COST IMPACTS TO PRIVATE PERSONS OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

The Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000. Therefore, the Board has prepared the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1), and included it in the initial statement of reasons. The Board has determined that the adoption of the proposed amendments to Regulation 1591 will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California. Furthermore, the Board has determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

NO SIGNIFICANT EFFECT ON HOUSING COSTS

The adoption of the proposed amendments to Regulation 1591 will not have a significant effect on housing costs.

DETERMINATION REGARDING ALTERNATIVES

The Board must determine that no reasonable alternative considered by it or that has been otherwise identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

CONTACT PERSONS

Questions regarding the substance of the proposed amendments should be directed to Bradley M. Heller, Tax Counsel IV, by telephone at (916) 323-3091, by e-mail at Bradley.Heller@boe.ca.gov, or by mail at State Board of Equalization, Attn: Bradley Heller, MIC:82, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, by telephone at (916) ~~4~~45-2130, by fax at (916) 324-3984, by e-mail at Richard.Bennion@boe.ca.gov, or by mail at State Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0080.

WRITTEN COMMENT PERIOD

The written comment period ends at 9:30 a.m. on April 28, 2015, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the April 28-30, 2015, Board meeting. Written comments

received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an underscored and strikeout version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are based are available to the public upon request. The rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed amendments and the initial statement of reasons are also available on the Board's Website at *www.boe.ca.gov*.

SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8

The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

AVAILABILITY OF FINAL STATEMENT OF REASONS

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at *www.boe.ca.gov*.